

## REMARKS/ARGUMENTS

Applicant responds herein to the Office Action dated December 24, 2008.

Claims 1-8, 10-31, and 33-37 are pending in the application.

The objection to the disclosure based on 35 USC 132(a) of impermissible addition of new matter has been obviated by the cancellation thereof and clarification, within the claims, of the nature of “non-attachment” as being a removable attachment.

Claims 1-8, 10-12 and 33-36 were rejected under 35 USC 103(a) as being unpatentable over Oberlander in view of Fenton, Jr. Claims 1-8 and 10-19 were rejected under 35 USC 103(a) as being unpatentable over Oberlander in view of Fenton, Jr. in view of Sasaki et al. Claims 1-8 and 10-20 were rejected under 35 USC 103(a) as being unpatentable over Oberlander in view of Fenton, Jr. in view of Sasaki et al and in view of Runck et al. Claims 1-8, 10-19 and 21 were rejected under 35 USC 103(a) as being unpatentable over Oberlander in view of Fenton, Jr. in view of Sasaki et al and in view of Runck et al. Claims 1-8, 10-12 and 22-30 were rejected under 35 USC 103(a) as being unpatentable over Oberlander in view of Fenton, Jr in view of Bone.

In response thereto, Applicant re-iterates the arguments made in the prior submission and submits that the Examiner's basis for summarily dismissing the arguments has been obviated. The claims have been amended to remove any basis for considerations of intended use and functional statements and has clearly set forth structural limitations in all of the claims not found in the prior art even in combination. These structural limitations positively obviate the use of the Oberlander and Fenton devices in the environment of sternum closure, as claimed, and preclude the specific structural elements, as claimed, as being disclosed, or even suggested by the references, even in combination.

In addition to the above and in detail, it is submitted that in the present invention, as set forth in independent claims 1 and 36, the attachment of the separated halves of the sternum takes place due to their reapproximation by virtue of bringing the anchors close across the sternum incision. This is carried out by simultaneous displacement of the anchors across the incision i.e. along the **direction which is orthogonal to longitudinal axes of the anchors**. In all cited references the attachment takes place due to **approximation of tissues/bones in the direction which is along the anchors**.

In Oberlander and Fenton the fixing element is:

- a) bonded to the anchors either before disposing the anchors in the tissue (Oberlander) or afterwards (Fenton), but in both references it is not separable from the anchors;
- b) is made of non rigid material (plastic) and can deform during disposing the anchors in the tissue (Oberlander) or during its bonding to the anchors (Fenton);
- c) is not hollowed for detachment from anchors and cannot be detached from anchors after the tissues have been fixed together.

In the present invention, as structurally claimed, the fixing element(s) is (are):

- a) not bonded to the anchors and is (are) intentionally separable from them;
- b) is made of rigid (metallic) material since it should not deform;
- c) is separable from anchors after the halves of the sternum are reapproximated.

Neither the Oberlander nor Fenton anchors are intended for reapproximating halves of the incised sternum and they are not capable of doing this even with the suggested combined teachings. The devices and anchors of Oberlander and of Fenton, as would be recognized by one skilled in the art, are intended for and designed for approximating the tissue along the direction of the anchors and not along a direction which is orthogonal to the anchors (as in the present claims).

The Examiner has alleged that the fixing means of Oberlander is shaped as a staple as claimed (Fig. 3 ref.31). This is however erroneous since element 31 is configured as a plastic, deformable suture and not as a rigid non-deformable staple. In addition, The Examiner has stated that the body of the suture is perpendicular to the legs thereof as claimed. This is however incorrect as seen in Fig. 13.

The present claims require that the legs of the staple are disposed in axial passages of anchors. In contrast, in Oberlander the legs of the suture are bonded to the anchor's body and do not and cannot enter in axial passages. Accordingly the Examiner's allegation that in Oberlander the legs are adapted for extraction from axial passages is incorrect. Since the legs are bonded to anchors and are not in the axial passages the legs could not be withdrawn from axial passages.

The amended claims further include the feature of rigid, metallic fixing elements and the feature of fixing apparatus without which it there is no possibility of reapproximating the halves of the sternum. The fixing apparatus is inter alia adapted to bring the anchors closer along a

direction, which is across the incision and then to secure the anchors in a position after the halves of the sternum have been brought closer. Neither Oberlander, nor Fenton discloses such fixing apparatus feature and therefore their alleged combination would not result in the present invention as claimed.

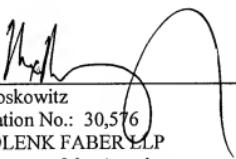
Claim 22, has been similarly amended with the fixing apparatus and new claim 37, which specifically recites the apparatus for removing the fixing elements has been added.

Accordingly, the Examiner is respectfully requested to reconsider the application, allow the claims as amended and pass this case to issue.

THIS CORRESPONDENCE IS BEING  
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